भारतीय मानक

Indian Standard

IS 18947 : 2024

होम्योपैथी में प्रयोग हेतु ग्लोब्यूल्स — विशिष्टि

Globules for Use in Homoeopathy — Specification

ICS 67.180.10

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Homoeopathy Sectional Committee, AYD 07

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Homoeopathy Sectional Committee had been approved by the Ayush Division Council.

Globules are solid round bead-like preparations made from sucrose or a combination of sucrose and lactose. However, this standard applies exclusively to pure sucrose globules. These are the most commonly used vehicle for dispensing homoeopathic medicines to be taken orally. By themselves, globules are non-medicated and are impregnated with liquid homoeopathic drugs to prepare medicated globules.

These globules, either in themselves or impregnated with plain dispensing alcohol, are the most commonly used form of placebo used in homoeopathic practice and research. Without a standard for these globules, the impregnation quality is variable. The possibility of adulterants is high, impacting the quality of the drug dispensed.

The standard is being brought out for the use of manufacturers and assurance to the researchers, practitioners, and patients that the quality of the drug dispensed is not compromised.

In formulating this standard, significant assistance has been derived from the Indian Standards published by the Government of India. Inputs have also been derived from the information available in the public domain in print and electronic media, including Homoeopathic Pharmacopoeia of India and U.S., French, European, Indian, and other Pharmacopoeias.

Also, due consideration has been given to the provisions of the *Drug and Cosmetics Act*, 1940 and the rules 1945, framed thereunder, including the latest amendments. In case of any disparity, this standard is subject to the restrictions imposed under these will be applicable.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

GLOBULES FOR USE IN HOMOEOPATHY — SPECIFICATION

1 SCOPE

1.1 This standard prescribes the description, and test methods, including packing and storage of pure sucrose globules.

1.2 The standard does not cover globules containing lactose in any proportion.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of these standards:

IS No.	*Title*
IS 1070 : 2023	Reagent grade water — Specification (*fourth revision*)
IS 10146 : 1982	Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water

3 TERMINOLOGY

For this document, the following terms and definitions shall apply.

3.1 Globules — Globules, also called pellets or pillules, are solid preparations made of pure pharma grade sucrose only. They are intended for the impregnation of homoeopathic medicines, used sublingually or orally.

4 REQUIREMENTS

4.1 Description

4.1.1 Globules shall be formed as small white homogenous and regular spheres of different sizes, designated according to the diameter of ten (10) globules in millimeters.

4.1.2 They shall not crumble or break on handling.

4.1.3 They shall be intended for impregnation or coating with homoeopathic preparations.

4.1.4 The globules shall be made of pharma-grade sucrose, inert, perfectly white, and odourless, having a sweet taste, and able to withstand all the tests prescribed for sucrose.

4.2 Size

Standard sizes are as in Table 1.

5 TEST METHODS

5.1 General Appearance

The globules shall be white-coloured uniform spheroids.

5.2 Solubility

5.2.1 Globules shall be entirely soluble in water.

5.2.2 Globules shall be insoluble in alcohol.

Table 1 Standard Sizes of Globules

(*Clause* 4.2)

Sl No.	Types of Globules	Size	Size mm
(1)	(2)	(3)	(4)
i)	Very small globules	10	0.9 mm to 1.1 mm
ii)	Small globules	20	1.8 mm to 2.2 mm
iii)	Regular globules	30	2.7 mm to 3.3 mm
		40	3.6 mm to 4.4 mm
iv)	Large globules	60	5.4 mm to 6.6 mm

5.3 Number of Globules per Gram

The number of globules per gram shall correspond to the category as per Table 2. Weigh about 1 g of globules and calculate number of globules/g.

$$\text{Number of globules/g} = \frac{\text{Number of globules}}{\text{Weight of globules (g)}}$$

5.4 Average Size

Variation in diameter shall be not more than (NMT) ± 10 percent. Measure the diameter of 10 globules using a vernier caliper and calculate the average diameter.

$$\text{Average size of globule (mm)} = \frac{\Sigma \text{ Diameter of globules (mm)}}{\text{Number of globules}}$$

5.5 Fineness

As indicated in Table 2, not less than 90 percent m/m of the globules shall be between the lower and upper limits of the corresponding category.

5.6 Uniformity of Mass

Carry out the test using 20 globules to constitute 1 unit. Weigh individually 20 units taken at random and determine the individual and average masses. Not more than two of the individual masses should deviate from the average mass by more than 10 percent, and none should deviate by more than 20 percent.

NOTE — If the test for fineness is carried out, the test for uniformity of mass need not be carried out, and vice versa.

5.7 Assay

5.7.1 *Sucrose content in globules*

It shall not be less than 99 percent of the claimed amount.

5.8 Optical Rotation

Acceptance criteria: + 66.3 to + 67.0

5.9 Identification Tests

5.9.1 *Solution Z*

Dissolve 10 g of globules in purified water and make up the volume to 100 ml. The solution shall be clear and colorless.

Table 2 Classification of Globules According to their Mass

(*Clause* 5.3 *and* 5.5)

Sl No.	Category	Number of Globules for Homoeopathic Preparations	Mass (g)	Fineness (µm)
(1)	(2)	(3)	(4)	(5)
i)	1	470 to 530	1.0	1 000 to 1 600
ii)	2	160 to 333	1.0	1 400 to 2 000
iii)	3	110 to 130	1.0	1 800 to 2 500
iv)	4	70 to 90	1.0	2 000 to 2 800
v)	5	40 to 50	1.0	2 500 to 3 350
vi)	6	16 to 30	1.0	3 150 to 4 500
vii)	7	10	0.9 to 1.1	4 000 to 5 600
viii)	8	5	0.9 to 1.1	5 600 to 6 700
ix)	9	3	0.9 to 1.1	7 100 to 8 000
x)	10	2	0.9 to 1.1	8 000 to 9 500

NOTE — For categories 7 to10, the mass is obtained by weighing the specified number of globules.

5.9.2 Add 3 ml of Tollens reagent to 3 ml of Solution Z and boil it. The presence of lactose shall be indicated by a black precipitate.

5.9.3 Add some Indole-3-acetic acid crystals to 5 ml of hydrochloric acid and five drops of Solution Z. Stir it. Let it rest. The presence of sucrose shall be indicated by a violet color.

5.9.4 Add 6 ml of 0.5 M sulphuric acid to 4 ml of Solution Z and heat for a minute; cool it down and neutralize on litmus paper with sodium hydroxide (8 percent m/v NaOH in water). Add 5 ml alkaline cupric tartrate SR and boil it for a minute. The presence of sucrose shall be indicated by brick-red precipitate.

5.10 *p*H (10 Percent *w/v* in Water)

Dissolve 10 g of inert globules in purified water and adjust the volume to 100 ml. The *p*H of the solution shall be between 5 and 7.

5.11 Loss on Drying

Take 2 g of the sample and dry it at 105 °C for 4 h. The loss on drying shall not be more than 4 percent w/w.

5.12 Impurities (Residue on Ignition)

Take a 2 g sample and ignite at a temperature of 700 °C ± 25 °C until charred thoroughly. The residue on ignition shall not be more than 0.25 percent w/w.

5.13 Foreign Matter

Globules shall be free from any flavor and foreign matter like kaolin, chalk, talc, starch, animal dander, inorganic, and any synthetic whitening agents. To test for these, prepare a 5 percent w/v Solution A from powdered globules (*see* Table 3).

5.14 Porosity

5.14.1 Put 1 to 2 drops of dispensing alcohol on the globule. Cut the globule with a sharp blade into two halves. Check the two halves for absorption. Impregnation of dispensing alcohol to the globule's center shall not be more than 50 seconds.

NOTE — The globule shall not dissolve in dispensing alcohol.

5.14.2 Put 1 to 2 drops of 0.1 percent methylene blue solution on the sphere (globule). Cut the globule with a sharp blade into two halves. Check the two halves for absorption. The impregnation of methylene blue solution to the sphere's center should not exceed 50 seconds.

5.15 Uniformity of Impregnation

None of the individual values shall deviate by more than 10 percent from the average of 10 determinations. Determine the uniformity of impregnation using either method A or method B. Carry out 10 individual determinations.

Table 3 Test Methods

(*Clause* 5.13)

Sl No.	Test	Method
(1)	(2)	(3)
i)	Kaolin test	Take 5 ml to 10 ml of Solution A in a conical flask, add a small amount of dilute ammonia solution, and allow to stand for 5 min. No white precipitate is observed.
ii)	Chalk test	Take 5 ml to 10 ml of Solution A, add a small amount of dilute ammonia oxalate solution, and allow to stand for 5 min. No white precipitate is observed. Take some powdered samples and add dilute hydrochloric acid. No effervescence is observed.
iii)	Talc test	Take 5 ml to 10 ml of Solution A, add a small amount of ammonium carbonate solution, and boil. No white precipitate is observed.
iv)	Starch test	Add iodine tincture solution to the sample Solution A, a violet to deep blue color is produced

5.15.1 *Method A — Methylene Blue*

a) Methylene blue impregnation solution

Use a freshly prepared solution. Dissolve 1 g of methylene blue R in 50 ml of ethanol (70 percent *v/v*) R and dilute to 1 000 ml with the same solvent.

b) Impregnation

Impregnate a suitable quantity of globules for homoeopathic preparations with a suitable quantity of the methylene blue impregnation solution to achieve a content of 10 µL of impregnation solution per gram of globules.

c) Test solution

Dissolve 5 g of the impregnated globules in water and dilute to 25 ml with the same solvent.

d) Reference solution

Dilute 1 ml of the methylene blue impregnation solution to 100 ml with water. To 5 ml of this solution, add 5 g of globules for homoeopathic preparations, dissolve in water R, and dilute to 25 ml with the same solvent. Measure the absorbance of the test solution and the reference solution at 665 nm. Calculate the percentage of impregnation of globules for homoeopathic preparations using the following expression:

$$\frac{A_1 \times 500}{A_2 \times m}$$

where

A_1 = absorbance of the test solution;

A_2 = absorbance of the reference solution; and

m = mass, of the impregnated globules used to prepare the test solution in grams.

5.15.2 *Method B — Caffeine*

As the test results are particularly influenced by the procedures for impregnation and drying of the globules, the parameters of these procedures are defined and stated with the result.

a) Caffeine Impregnation Solution Prepare a 15 g/L solution of caffeine R in ethanol (70 percent *v/v*).

b) Impregnation

Impregnate a suitable quantity of globules for homoeopathic preparations with a suitable quantity of the caffeine impregnation solution to achieve a content of 10 µL of impregnation solution per gram of globules. While preparing the following solutions, if the globules are not fully dissolved, sonicate the dispersion for 30 min and cool to 20 °C. Before measuring the absorbance, centrifuge the dispersion and filter the supernatant through a membrane filter (nominal pore size 0.45 µm).

c) Test solution

To 5 g of the impregnated globules, add 30 ml of water R. Shake manually, then sonicate until complete dissolution of the globules. Dilute to 50 ml with water.

d) Reference solution

Dilute 1 ml of the caffeine impregnation solution to 100 ml with water. To 5 ml of this solution, add 5 g of globules for homoeopathic preparations and 30 ml of water R. Shake manually, then sonicate until complete dissolution of the globules. Dilute to 50 ml with water.

e) Compensation liquid

To 5 g of globules for homoeopathic preparations, add 30 ml of water. Shake manually, then sonicate until the globules are completely dissolved. Dilute to 50 ml with water. Measure the absorbance of the test solution and the reference solution at 273 nm compared with the compensation liquid. Calculate the percentage of impregnation of the globules for homoeopathic preparations using the following expression:

$$\frac{A_1 \times 500}{A_2 \times m}$$

where

A_1 = absorbance of the test solution;

A_2 = absorbance of the reference solution; and

m = mass, of the impregnated globules used to prepare the test solution in grams.

5.16 Microbial Contamination

The total aerobic microbial count (TAMC) shall be equivalent to the number of colony-forming units (CFU) found using a general medium (nutrient agar) for bacterial growth. The total combined yeasts/mould count (TYMC) shall be equivalent to the number of CFU found using the SDA medium. The values shall be as per Table 4.

NOTE — Quality of reagents.

Unless specified otherwise, analytical-grade reagents and distilled water (*see* IS 1070) shall be used in tests.

6 SHELF LIFE

A shelf life of 3 years is recommended, subject to data as per in-house stability studies.

7 PACKING, MARKING AND STORAGE

7.1 Packing

The material shall be packed in clean, sound, and dry containers of food-grade non-reactive metal alloy, glass, or polymers. The container shall be free from any fungal or insect infestation and not impart any foreign odour. Each container shall be securely closed and sealed. They can also be packed in airtight plastic bags in secondary packaging of cartons as per IS 10146.

7.2 Marking

7.2.1 The packaging shall be securely closed and marked with the following particulars, legibly and indelibly:

a) Name and address of the manufacturer or packer, including contact details;

b) Name of the material;

c) Size of globules;

d) Net quantity;

e) Manufacturer's license no.;

f) Date of manufacturing;

g) Date of packing;

h) Best before date;

j) Batch or code number;

k) Trade name or brand name, if any; and

m) Any other information requested by the buyer.

7.2.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

7.3 Storage

The material shall be stored in clean and dry containers of food-grade non-reactive metal alloy or polymers at room temperature, away from the sources of heat and moisture.

8 SAMPLING

Representative material samples shall be drawn and tested for conformity to this specification in accordance with the procedure prescribed in Annex A.

Table 4 Microbial Contamination

(*Clause* 5.16)

Sl No.		TAMC	TYMC	Specified Microorganism(s)	
(1)	(2)	(3)	(4)	(5)	
i)	*Acceptance criteria*	10^2 CFU/g	10^1 CFU/g	Absent *Staphylococcus aureus*	Absent *Pseudomonas aeruginosa*

ANNEX A

(*Clause* 8)

SAMPLING OF GLOBULES

A-1 GENERAL REQUIREMENTS OF SAMPLING

A-1.1 The following precautions and directions shall be observed in drawing, preparing, storing, and handling samples.

A-1.2 Samples shall be taken in a protected place and not exposed to damp air, dust, or soot.

A-1.3 The sampling instruments shall be clean and dry when used.

A-1.4 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument, and the containers of samples from adventitious contamination.

A-1.5 The samples shall be placed in clean and dry glass containers. The sample containers shall be of such a size that they are almost completely filled by the sample. The samples shall be filled loose and not pressed in the container.

A-1.6 Each container shall be sealed air-tight after filling and marked with full details of sampling, date of sampling, batch or code number, name of the manufacturer, and other important particulars of the consignment.

A-1.7 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

A-2 SCALE OF SAMPLING

A-2.1 *Lot*

All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If the consignment is declared to consist of different batches of manufacture, the batches shall be marked separately, and the groups of containers in each shall constitute separate lots. Samples shall be tested for each lot to ascertain its conformity to the requirements of the corresponding specification.

A-2.3 Containers shall be selected randomly from the lot using systematic random sampling. To determine the sample size, calculate $n = \sqrt{N+1}$, where N is the total number of containers in the lot and n is the required sample size. Starting from any container in the lot, count them as 1, 2, 3, up to 10 in a systematic manner. Calculate r, the sampling interval, as the integer part of N/n, every r^{th} container thus counted shall be separated until the requisite number of n containers is obtained from the lot to give the sample for the test.

A-3 Test Samples and Referee Sample

A-3.1 From each of the selected containers, with the help of a suitable sampling instrument, approximately equal quantities of material shall be taken out so as to make a composite sample of about 1 kg. This sample shall be thoroughly mixed and divided into three equal parts, transferred to clean and dry glass containers, sealed air-tight, and labeled with particulars as given in **A-1.6**. One of these composite samples shall be for the purchaser, another for the vendor, and the third for the referee.

NOTE — In case the materials of various types are packed in the same container, the material of each type shall be separated, the sample shall be prepared as given in **A-3.1** and tested for conformity to requirements carried out for each other

A-3.2 Referee sample — The referee sample shall consist of the composite sample marked for this purpose and shall bear the seal of the purchaser and the vendor which shall be kept at a place as agreed to between the two. This shall be used in case of a dispute between the purchaser and the vendor.

A-4 Number of Tests and Criteria for Conformity

Test and criteria for conformity are as prescribed in 5.

A-4.1 All the requirements of the corresponding specification shall be tested on the composite sample.

A-4.2 The lot shall be declared as conforming to the specification when the composite sample tested for various requirements satisfies the correspondence requirement of the specification.

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

Homoeopathy Sectional Committee, AYD 07

Organization	*Representative*(*s*)
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Dr DP Rastogi Central Research Institute of Homoeopathy, Noida	DR BINIT DWIVEDI DR ANAMIKA KOTIYA

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Amendments Issued Since Publication

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